these paragraphs.

RESPONSE

Final Rejection Status

The application is presently under "final" rejection.

1) The applicant respectfully requests that final rejection be withdrawn per MPEP 706.07(c). The reasons that the applicant states that final rejection may be premature are as follows. MPEP 706.07(a) (version MPEP_e8r2_700_508) states as follows (at page 700-75, the first complete paragraph):

> A second or any subsequent action on the merits in any application or patent involved in reexamination proceedings should not be made final if it includes a rejection, on prior art not of record, of any claim amended to include limitations which should reasonably have been expected to be claimed. See MPEP § 904 *et seq.* For example, one would reasonably expect that a rejection under 35 U.S.C. 112 for the reason of incompleteness would be replied to by an amendment supplying the omitted element.

The present application includes a new rejection on the basis of prior art not of

previous record (US Patent No. 4282863, "Beigler", not made of record until the Second Office Action to which this is the first reply) of a claim amended (in this Response and Amendment of August 2005) to include limitations which should reasonably have been expected to be claimed. In particular, a rejection under 35 USC 112 is made in the Second Office Action of claims 1-21 and 29, according to the Second Office Action, on the grounds that "It is unclear whether the claims are directed to a single composition or a kit of separate compositions." (Either of claims 22 through 24 inclusive, or else claim 25 by itself, do not suffer this problem, as the examiner has refrained from citing them under this 35 USC 112 rejection. The present amendment includes these limitations in the independent claims 1 and 29.) The applicant notes that in the First Office Action, the examiner raised a number of other 35 USC 112 rejections, but not this one directed to the issue of "single composition or kit", and thus this is the first opportunity for the applicant to respond to this ground for rejection. Yet to quote (id), "For example, one would reasonably expect that a rejection under 35 U.S.C. 112 for the reason of incompleteness would be replied to by an amendment supplying the omitted element."

2. Even if the examiner feels that "final" status is justified despite the 35 USC 112 rejection of claims rejected under art not previously of record, the examiner may consider the following Response and Amendment and grant the application to "allowed" status without reconsideration of the "final" status. In particular, 37

CFR 1.116(c) states as follows:

> If amendments touching the merits of the application or patent under reexamination are presented after final rejection, or after appeal has been taken, or when amendment might not otherwise be proper, they may be admitted upon a showing of good and sufficient reasons why they are necessary and were not earlier presented.

Thus, the present amendments may be admitted under "final" rejection "on a showing of good and sufficient reasons why they are necessary and were not earlier presented."

The present amendments, to include the limitations of claims 22 through 24 into independent claims 1 and 29, are necessary, according to the examiner's statement in the Second Office Action, because "it is unclear whether the claims are directed to a single composition or a kit of separate compositions." Thus, the examiner's statement may reasonably considered to show that the amendments are necessary. (And as noted earlier, the MPEP states that this expectation of amendment is reasonable.)

The required showing as to "why the amendments were not earlier raised" is met since the examiner has only in the most recent Second Office Action raised the

rejection under 35 USC 112 regarding this question of "single composition or kit". The applicant notes that in the First Office Action, the examiner raised a number of other 35 USC 112 rejections, but not this one, and thus this is the first opportunity for the applicant to respond to this ground for rejection, and thus the amendment could not be made earlier.

On this basis, the applicant will proactively submit this response and the accompanying amendments.

Rejection of claims 1-18, 21-27, and 29 under 35 USC 103(a) over the '863 reference

The examiner presently rejects claims 1-18, 21-27 and 29 over the '863 reference, "Beigler". However, a number of limitations of these claims are not met.

1) Most importantly, the '863 reference does not teach an anti-craving medication, but rather a nutrient. One extremely significant aspect of the present application is the presentation of an intravenous anti-craving medication, while the reference art teaches an intravenous nutrient mix. Thus the '863 reference is simply not relevant prior art.

2) As a result of the fact that the '863 reference being a nutrient mix and not an anti-craving medication, it fails to teach important structural limitations of the present invention. In particular, the selected forms of the selected vitamins, minerals and

amino acids are selected according to the following structural limitation of claim 1: **"said agents being selected for their combined ability to reduce craving, and said agents further being selected so as to allow efficient use of the medication by such body of an individual suffering from substance abuse."**

These are significant and genuine limitations. For example, "EXAMPLE 5" of the '863 reference teaches use of the "L" form of phenylalanine, a useful nutrient, but the present invention teaches that the "DL" form or "D" forms are found superior for anti-craving purposes (without wishing to be bound by any particular theory, this might be due to the pain control properties of these latter forms or may be due to some inherent anti-craving ability), and indeed the "L" form has in some testing been found not to have this strong anti-craving effect.

As another example of the deficiencies of the '863 reference, "EXAMPLE 3" of the '863 reference (not "TABLE 3") teaches the use of Calcium Gluconate: this is a natural addition to a nutrient mixture. However, the present application teaches that the use of Calcium in all forms should be avoided, as it inhibits the overall efficacy of the anti-craving medication. (See the Background of the Invention of the present application).

Similar arguments may be made for the use of sugars such as glucose and dextrose, which have also previously been discussed, (for example, from the

Application as originally filed: "Glucose and fructose solutions are not feasible for use in administering via IV drip multiple amino-acid medicines. First, the sugars "spike" the levels of the neurotransmitters in the brain much like the abused substance . . . thus included sugars would function as "agonists", reducing the craving temporarily by briefly satisfying it rather than by returning the brain to normal functioning. Second, fructose and glucose act much like calcium does, driving amino-acids into the muscle tissues rather than across the blood/brain barrier, and furthermore this undesirable activity is promoted by the presence of chromium and niacin, which are important agents for other reasons. Thus a saline solution is preferred." Driving amino-acids into muscle tissue is acceptable for a nutrient mix such as the '863, but it is **not** acceptable for an anti-craving composition which must reach the brain. Others of the ingredients of the '863 mixes may be similarly analyzed. **In short, the nutrient mixtures of the '863 reference are *not* selected for ability to reduce craving and for efficient metabolization by the bodies of individuals suffering from substance abuse symptoms.** In fact the '863 reference actually teaches away from such selection by teaching these nutrients which are not beneficial medications for substance abuse sufferers.

The applicant will not belabor the many portions of the application as originally filed and the Response and Amendment of January 2005, which discuss at great length the need for the selected agents to reduce craving nor the even longer

portions of the application which dealt with the issue of "metabolic by-pass". An example is the first sentence of the first paragraph of the detailed description: "The invention provides an anti-craving medication whose active agents are selected to overcome the physical barriers to efficient use which exist in the bodies of individuals suffering from substance abuse..." which then continues through several more pages, including: ""Metabolic by-pass" is crucial to the invention, this term includes by-pass of the liver ("liver by-pass"), stomach lining by-pass, intestinal lining by-pass, minimal use of the pancreatic juices, and the ability to cross the blood/brain barrier without reliance on metabolic resources. Agents are selected based upon their ability to by-pass metabolic processes. In particular, forms of the agents which can best by-pass metabolic processes are selected over forms which do not so easily do so."

The present invention includes, in claim 1, a limitation laid out in great detail in the application as originally filed: that the agents selected and the forms of those agents selected will be selected for their ability to reduce craving. **The '863 reference discusses in great detail other and different grounds for selection of its own different selection of ingredients, and yet this crucial anti-craving selection limitation is nowhere to be found in the '863 reference.**

3) The '863 reference does not teach a plurality of components. That is, the '863 reference teaches a single "dry intravenous bag" of nutrients which may have

water added to. Interestingly, the '863 reference teaches a number of different individual compositions, some of which individually include vitamins, minerals or amino acids. The '863 reference even teaches that a single component (a single bag) may contain a mixture of nutrients of all three types. However, the '863 reference does not teach that three components may be used. In fact, since the '863 reference teaches combination of the three families of agents into a single bag it actually teaches away from the use of three different components, one for vitamins, one for minerals, and one for amino acids. This is a fairly subtle distinction: the '863 reference teaches a single component of either vitamins, or minerals, or amino acids, or even all three (claim 10 of the reference). But the '863 reference does NOT teach a three component system, instead, it teaches towards the use of the single component, in fact, this is a primary goal of the '863 reference, a fact which may be verified by recourse to the

For all of the foregoing reasons, claims 1 and 29 and those claims dependent thereon are in condition for immediate allowance, and such action is earnestly requested.

Rejection of claims 19 and 20 under 35 USC 103

The examiner presently rejects claims 19 and 20 over combinations of the '863 reference and other art showing compounds similar to the agents of the present invention. However, since these two claims are dependent upon a base claim (claim 1) having limitations not shown in the prior art, these claims are themselves allowable and these

grounds for rejection are mooted. In addition, in the chemical arts, it is well established that small differences may lead in to patentably distinct products due to the inherent difficulty of predicting chemical behavior.

For all the foregoing reasons, claims 19 and 20 are in condition for immediate allowance, and such action is respectfully requested.

Rejection of claims 1-21 and 29 under 35 USC 112

The examiner has stated that those claims not citing specifically whether a single component comprises a single vial of medication ("single composition or kit") are unsuitable for allowance. The applicant's invention is a three vial / three composition medication which taken together as a single medication have been tested to provide a single anti-craving medication having high efficiency in the clinical setting of real world substance abusers.

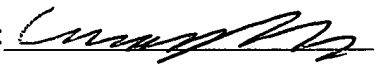
The applicant has noted that the claims 22 through 24 (or in the alternative, claim 25 standing alone) are exempted from this rejection and thus has incorporated the operative language of these claims into claims 1 and 29, thus mooting this ground for rejection.

For all the foregoing reasons, claims 1 and 29 are in condition for immediate allowance, and such action is respectfully requested.

Conclusion

For all the foregoing reasons, applicant respectfully urges that the application is now in condition for immediate allowance, and such action is requested. The examiner is respectfully urged to contact applicant's counsel, Craig W. Barber, PO Box 16220, Golden, Colorado, 80402-6004, 303-278-9973, fax 303-278-9977, with any questions or comments or examiner's amendments.

The applicant sincerely thanks Examiner Webman for his time on this matter.

Signed: 

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CLAIMS AS AMENDED JANUARY, 2005

1. (Currently Amended) An intravenous anti-craving medication for administration to the body of an individual suffering from substance abuse, said medication comprising: i) a first component comprising of the following agents: selected forms of selected amino-acids, selected so as to allow said first component to be a first single vial of intravenous medication ii) a second component comprising of the following agents: selected forms of selected vitamins, selected so as to allow said second component to be a second single vial of intravenous medication and iii) a third component comprising of the following agents: selected forms of selected minerals, selected so as to allow said third component to be a third single vial of intravenous medication;
said agents being selected for their combined ability to reduce craving, and said agents further being selected so as to allow efficient use of the medication by such body of an individual suffering from substance abuse.

2. (Previously Amended) The anti-craving medication of claim 1, wherein said selection of said agents so as to allow efficient use of the medication by the body of an individual suffering from substance abuse further comprises: selection based upon said agents' combined ability to promote crossing of the blood/brain barrier by at least one of said agents.

3. (Original) The anti-craving medication of claim 1, wherein said selection of said agents so as to allow efficient use of the medication by the body of an individual suffering from

substance abuse further comprises: selection based upon said agents' abilities to promote liver by-pass by at least one of said agents.

4. (Original) The anti-craving medication of claim 1, wherein said selection of said agents so as to allow efficient use of the medication by the body of an individual suffering from substance abuse further comprises: selection based upon said agents' abilities to promote stomach lining by-pass by at least one of said agents.

5. (Original) The anti-craving medication of claim 1, wherein said selection of said agents so as to allow efficient use of the medication by the body of an individual suffering from substance abuse further comprises: selection based upon said agents' combined ability to promote intestinal lining by-pass by at least one of said agents.

6. (Original) The anti-craving medication of claim 1, wherein said selection of said agents so as to allow efficient use of the medication by the body of an individual suffering from substance abuse further comprises: selection based upon said agents' combined ability to promote,

i) crossing of the blood/brain barrier by at least one of said agents,

ii) liver by-pass by at least one of said agents,

iii) stomach lining by-pass by at least one of said agents, and

iv) intestinal lining by-pass by at least one of said agents.

7. (Original) The anti-craving medication of claim 1, wherein said selection of forms of

selected amino acids further comprises: preferentially selecting forms of said selected amino-acids which easily cross the blood/brain barrier ~~baffler~~.

8. (Original) The anti-craving medication of claim 7, wherein said selection of forms of selected amino acids further comprises: preferentially selecting isomers of said selected amino-acids having the ability to easily cross the blood/brain barrier.

9. (Previously Amended) The anti-craving medication of claim 1, wherein said first component further comprises: at least three amino-acids.

10. (Original) The anti-craving medication of claim 1, wherein said selection of said forms of said minerals further comprises: selecting molecular forms of the minerals having small size.

11. (Original) The anti-craving medication of claim 1, wherein said selection of said forms of said minerals further comprises: selecting mineral forms which are water soluble.

12. (Original) The anti-craving medication of claim 1, wherein said selection of said forms of said minerals further comprises: selecting mineral forms which are cellularly active.

13. (Original) The anti-craving medication of claim 1, wherein said selection of said forms of said minerals further comprises: selectively avoiding usage of forms of said minerals which release calcium while being metabolized, whereby efficient use of the medication

by such body of an individual suffering from substance abuse is promoted.

14. (Previously Amended) The anti-craving medication of claim 1, wherein said selection of said forms of said minerals further comprises: selecting minerals in sulfate form.

15. (Previously Amended) The anti-craving medication of claim 1, wherein said selection of said forms of said minerals further comprises: selecting non-chelate mineral forms.

16. (Previously Amended) The anti-craving medication of claim 1, wherein said third component further comprises: at least four minerals.

17. (Original) The anti-craving medication of claim 1, wherein said agents selected so as to allow efficient use of the medication by the body of an individual suffering from substance abuse further comprises: selecting vitamin forms which are water soluble.

18. (Original) The anti-craving medication of claim 1, wherein said agents selected so as to allow efficient use of the medication by the body of an individual suffering from substance abuse further comprises: selecting vitamin forms which are cellularly active.

19. (Previously Amended) The anti-craving medication of claim 1, wherein said second component further comprises: riboflavin-5-phosphate sodium whereby efficient use of the medication by such body of an individual suffering from substance abuse is promoted.

20. (Original) The anti-craving medication of claim 1, wherein said third component further comprises: methylcobolamin, whereby efficient use of the medication by such body of an individual suffering from substance abuse is promoted.

21. (Previously Amended) The anti-craving medication of claim 1, wherein said third component further comprises: at least three vitamins.

22. (Previously Amended) The anti-craving medication of claim 1, wherein said selection of said agents of said first component further comprises: selecting said agents so as to allow said first component to be a single vial of intravenous medication.

23. (Original) The anti-craving medication of claim 1, wherein said selection of said agents of said second component further comprises: selecting said agents so as to allow said second component to be a single vial of medication suitable for intravenous administration.

24. (Original) The anti-craving medication of claim 1, wherein said selection of said agents of said third component further comprises: selecting said agents so as to allow said third component to be a single vial of medication suitable for intravenous administration.

25. (Previously Amended) The anti-craving medication of claim 1, wherein said selection of said agents of each of said first, second and third components further comprises: selecting said agents so as to allow each of said first, second and third components to be a

single vial of intravenous medication, whereby a total of only three vials must be administered to such patient suffering from substance abuse.

26. (Original) The anti-craving medication of claim 25, wherein each of said components is introduced into a saline solution.

27. (Previously Amended) The anti-craving medication of claim 26, wherein said saline solution is adjusted to maintain an osmolarity in the range between approximately 210 mOsm/l and approximately 300 mOsmll.

28. (Cancelled)

29. (Currently Amended) An intravenous anti-craving medication for administration to the body of an individual suffering from substance abuse, said medication comprising: i) a first component comprising of the following agents: selected forms of selected amino-acids, selected so as to allow said first component to be a first single vial of intravenous medication ii) a second component comprising of the following agents: selected forms of selected vitamins, selected so as to allow said second component to be a second single vial of intravenous medication and iii) a third component comprising of the following agents: selected forms of selected minerals, selected so as to allow said third component to be a third single vial of intravenous medication;
said agents being selected for their combined ability to reduce craving, and said agents further being selected so as to require minimal metabolic processing of said agents by

such body of individual suffering from substance abuse prior to the agents taking effect in the brain of such individual.

30. (Cancelled)

31. (Cancelled)

32. (Cancelled)

33. (Cancelled)

34. (Cancelled)

35. (Cancelled)

36. (Cancelled)

37. (Cancelled)

38. (Cancelled)

39. (Cancelled)